Constituent	CAS No.	RAC (μg/m³)
Maleic anhydride	108-31-6	100
Mercury	7439-97-6	2
Methacrylonitrile	126-98-7	0.1
Methomyl	16752-77-5	20
Methoxychlor	72-43-5	50
Methyl Chlorocarbonate	79-22-1	1000
Methyl Ethyl Ketone	78-93-3	80
Methyl Parathion	298-00-0	0.3
Nickel Cyanide	557-19-7	20
Nitric Oxide	10102-43-9	100
Nitrobenzene	98-95-3	0.8
Pentachlorobenzene	608-93-5	0.8
Pentachlorophenol	87-86-5	30
Phenol	108-95-2	30
M-phenylenediamine	108-45-2	5
Phenylmercuric Acetate	62-38-4	0.075
Phosphine	7803-51-2	0.3
Phthalic Anhydride	85-44-9	2000
Potassium Cyanide	151-50-8	50
Potassium Silver Cyanide	506-61-6	200
Pyridine	110-86-1	1
Selenious Acid	7783-60-8	3
Selenourea	630-10-4	5
Silver	7440-22-4	3
Silver Cyanide	506-64-9	100
Sodium Cyanide	143-33-9	30
Strychnine	57-24-9	0.3
1,2,4,5-tetrachlorobenzene	95-94-3	0.3
2,3,4,6-tetrachlorophenol	58-90-2	30
Tetraethyl Lead	78-00-2	0.0001
Tetrahydrofuran	109-99-9	10
Thallic Oxide	1314-32-5	0.3
Thallium	7440-28-0	0.5
Thallium (I) Acetate	563-68-8	0.5
Thallium (I) Carbonate	6533-73-9	0.3
Thallium (I) Chloride	7791-12-0	0.3
Thallium (I) Nitrate	10102-45-1	0.5
Thallium Selenite	12039-52-0	0.5
Thallium (I) Sulfate	7446-18-6	0.075
Thiram	137-26-8	5
Toluene	108-88-3	300
1,2,4-trichlorobenzene	120-82-1	20
Trichloromonofluoromethane	75-69-4	300
2,4,5-trichlorophenol	95-95-4	100
Vanadium Pentoxide	1314-62-1	20
Warfarin	81-81-2	0.3
Xylenes	1330-20-7	80
Zinc Cyanide	557-21-1	50
Zinc Phosphide	1314-84-7	0.3

Appendix J: Unit Risks for Carcinogenic Constituents

Constituent	CAS No.	Unit risk (m³/μg)
Acrylamide	79-06-1	1.3E−03
Acrylonitrile	107-13-1	6.8E−05
Aldrin	309-00-2	4.9E−03
Aniline	62-53-3	7.4E−06
Arsenic	7440-38-2	4.3E−03
Benz(a)anthracene	56-55-3	8.9E−04
Benzene	71-43-2	8.3E−06
Benzidine	92-87-5	6.7E−02
Benzo(a)pyrene	50-32-8	3.3E−03
Beryllium	7440-41-7	2.4E−04
Bis(2-chloroethyl)ether	111-44-4	3.3E−04
Bis(chloromethyl)ether	542-88-1	6.2E−02
Bis(2-ethylhexyl)phthalate	117-81-7	2.4E−07
1,3-butadiene	106-99-0	2.8E−04
Cadmium	7440-43-9	1.8E−03
Carbon Tetrachloride	56-23-5	1.5E−05
Chlordane	57-74-9	3.7E−04
Chloroform	67-66-3	2.3E−05
Chloromethane	74-87-3	3.6E−06
Chloromethyl Methyl Ether	107-30-2	
Chromium VI	7440-47-3	1.2E−02
DDT	50-29-3	9.7E−05
Dibenz(a,h)anthracene	53-70-3	1.4E−02
1,2-dibromo-3-chloropropane	96-12-8	6.3E−03
1,2-dibromoethane	106-93-4	2.2E−04
1,1-dichloroethane	75-34-3	2.6E−05
1,2-dichloroethane	107-06-2	2.6E−05
1,1-dichloroethylene	75-35-4	5.0E−05
1,3-dichloropropene	542-75-6	3.5E−01
Dieldrin	60-57-1	4.6E−03
Diethylstilbestrol	56-53-1	1.4E−01
Dimethylnitrosamine	62-75-9	1.4E−02
2,4-dinitrotoluene	121-14-2	8.8E−05
1,2-diphenylhydrazine	122-66-7	2.2E−04
1,4-dioxane	123-91-1	1.4E−06
Epichlorohydrin	106-89-8	1.2E−06
Ethylene Oxide	75-21-8	1.0E−04
Ethylene Dibromide	106-93-4	2.2E−04
Formaldehyde	50-00-0	1.3E−05
Heptachlor	76-44-8	1.3E−03
Heptachlor Epoxide	1024-57-3	2.6E−03
Hexachlorobenzene	118-74-1	4.9E−04
Hexachlorobutadiene	87-68-3	2.0E−05
Alpha-hexachlorocyclohexane	319-84-6	1.8E−03
Beta-hexachlorocyclohexane	319-85-7	5.3E−04
Gamma-hexachlorocyclohexane	58-89-9	3.8E−04
Hexachlorocyclohexane, Technical		5.1E−04
Hexachlorodibenzo-p-dioxin (1,2 Mixture)		1.3E+00
Hexachloroethane	67-72-1	4.0E−06
Hydrazine	302-01-2	2.9E−03
Hydrazine Sulfate	302-01-2	2.9E−03
3-methylcholanthrene	56-49-5	2.7E−03
Methyl Hydrazine	60-34-4	3.1E−04
Methylene Chloride	75-09-2	4.1E−06
4,4'-methylene-bis-2-chloroaniline	101-14-4	4.7E−05
Nickel	7440-02-0	2.4E−04
Nickel Refinery Dust	7440-02-0	2.4E−04
Nickel Subsulfide	12035-72-2	4.8E−04
2-nitropropane	79-46-9	2.7E−02
N-nitroso-n-butylamine	924-16-3	1.6E−03
N-nitroso-n-methylurea	684-93-5	3.5E−01
N-nitrosodiethylamine	55-18-5	4.3E−02
N-nitrosopyrrolidine	930-55-2	6.1E−04
Pentachloronitrobenzene	82-68-8	7.3E−05
PCBs	1336-36-3	1.2E−03
Pronamide	23950-58-5	4.6E−06
Reserpine	50-55-5	3.0E−03
2,3,7,8-tetrachlorodibenzo-p-dioxin	1746-01-6	4.5E+01
1,1,2,2-tetrachloroethane	79-34-5	5.8E−05
Tetrachloroethylene	127-18-4	4.8E−07
Thiourea	62-56-6	5.5E−04
1,1,2-trichloroethane	79-00-5	1.6E−05
Trichloroethylene	79-01-6	1.3E−06
2,4,6-trichlorophenol	88-06-2	5.7E−06
Toxaphene	8001-35-2	3.2E−04
Vinyl Chloride	75-01-4	7.1E−06

[FR Doc. 89-25022 Filed 10-25-89; 8:45 am]
BILLING CODE 6560-50-M

Federal Register

Thursday
October 26, 1989

Part IV

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 801

Medical Devices; Labeling for Menstrual Tampons; Ranges of Absorbency; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 801

[Docket No. 86N-0479]

RIN 0905-AC54

Medical Devices; Labeling for Menstrual Tampons; Ranges of Absorbency

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to amend its menstrual tampon labeling regulation to standardize each of the terms currently used to describe tampon absorbency, junior, regular, super, and super plus, so that each term represents a 3-gram range of absorbency. The rule requires that manufacturers describe absorbency using the term that corresponds to the absorbency of their tampons as determined by a test method specified in the final rule. The purpose of the final rule is to enable consumers to compare the absorbency of one brand and style of tampons with the absorbency of all other brands and styles.

Labeling of tampons to allow consumers to compare the absorbency of different brands and styles is important because the use of tampons is associated with toxic shock syndrome (TSS), a rare but serious and sometimes fatal disease, and the risk of contracting TSS increases with the use of tampons of higher absorbency. FDA is issuing this rule under the Federal Food, Drug, and Cosmetic Act (the act).

FDA is also announcing its final response to a citizen petition submitted by the Public Citizen Health Research Group (HRG) concerning absorbency labeling for tampons.

EFFECTIVE DATES: The final rule is effective for packages of tampons initially introduced or initially delivered for introduction into commerce after March 1, 1990. In accordance with 5 U.S.C. 552(a), the Director of the Office of the Federal Register approves the incorporation by reference of the voluntary standard referred to in 21 CFR 801.430(f)(2); this approval is effective on March 1, 1990.

FOR FURTHER INFORMATION CONTACT: Les Weinstein, Center for Devices and Radiological Health (HFZ-84), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4874.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 23, 1988 (53 FR 37250) (corrected November 3, 1988 (53 FR 44551, and January 17, 1989 (54 FR 1844)), FDA proposed to amend its current regulation governing user labeling for menstrual tampons (21 CFR 801.430) to require uniform absorbency testing of tampons and to standardize a method of expressing absorbency on tampon package labels. The agency proposed such testing and labeling requirements to enable consumers to make interbrand comparisons and choose the least absorbent tampon needed to control menstrual flow and, thus, reduce their risk of TSS.

Interested persons were given until December 22, 1988, to submit written comments on the proposal. The agency received more than 270 comments from tampon manufacturers, individual consumers, consumer groups, health care professionals, and researchers. After analyzing the comments concerning the agency's proposal to use a system of letters to represent absorbency ranges and not to standardize currently used terms of absorbency (e.g., regular, super, and super plus), the agency decided to issue a reproposal that would have replaced the letter designations with six absorbency terms that were different from, and would have been used in addition to, existing terms. The new terms (low absorbency, medium absorbency, medium-high absorbency, high absorbency, very high absorbency, and highest absorbency) corresponded to the six absorbency ranges described in the initital proposal (53 FR 37250). The reproposal, which was published in the **Federal Register** of June 12, 1989 (54 FR 25076) (corrected June 28, 1989 (54 FR 27188)), also would have required that the new terms be placed on the principal display panel of tampon packages to minimize any confusion that might have been created by the continued use of existing nonstandardized terms.

The reproposal included a summary of the comments received on the September 1988 proposed rule and the agency's response to them, and a tentative response to a citizen petition submitted by the Public Citizen Health Research Group concerning absorbency labeling for tampons. Interested persons were given until August 11, 1989, to submit written comments on the reproposal.

The agency received 39 comments on the reproposal from tampon manufacturers, individual consumers, consumer groups, and health care professionals. A summary of these comments and the agency's response to them are set out in section II of this preamble.

II. Summary and Analysis of Comments

A. General Comments

1. Almost all the comments, including those from tampon manufacturers, continued to support FDA's overall goal to ensure that absorbency information is provided to consumers. Specific suggestions included in the comments on how to improve the reproposed rule to provide the most truthful, accurate, and nonmisleading information on tampon absorbency are addressed in subsequent sections of this preamble.

FDA concludes, on the basis of the data and information discussed and cited, and for the reasons set out in the preamble to both the proposed rule and the reproposed rule and in this preamble, and taking into account the data, information, and views presented in the comments, that a final rule should be issued. As intended, the final rule will enable consumers to compare the absorbency of one brand and style of tampons with the absorbency of all other brands and styles, to choose the lowest absorbency needed to control menstrual flow, and, as a result, to reduce their risk of TSS.

2. One comment addressed the proposed revision of the estimated incidence of TSS included in current 21 CFR 801.430(d)(2). This comment noted that much of the data on which FDA bases that estimate were published in 1980 and 1981, and that the composition of many tampons has changed since then. The comment recommended that FDA use only the most up-to-date published incidence rates (as cited in 54 FR 25076 at 25079, approximately 1 to 2 cases of TSS per 100,000 menstruating girls and women per year) and should disregard the earlier published data (as cited in the **Federal Register** of June 22, 1982 (47 FR 26982), between 6 and 17 cases of TSS per 100,000 menstruating girls and women per year).

As stated in the preamble to the reproposed rule (54 FR 25076 at 25079), FDA believes that the actual incidence of TSS can only be estimated, and that it is appropriate to convey to consumers the full range of reasonable estimates. There must be a rational basis for the agency to choose one estimate over another. FDA does not agree that the suggestion that the composition of many tampons has changed over the years provides such a basis. Therefore, FDA has concluded that the estimated incidence of TSS in current § 801.430(d)(2) should be revised as

proposed. The final rule states that estimate of TSS to be from 1 to 17 cases per 100,000 menstruating girls and women per year.

3. Two manufacturers commented on FDA's statement in the preamble to the reproposed rule (54 FR 25076 at 25079) that tampons are misbranded under section 502(f)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 352(f)(1)), because current tampon labeling does not contain any information with which a woman can determine relative absorbency of different brands of tampons. One manufacturer noted that FDA had attempted to clarify this issue, but recommended that, to avoid any possible confusion and misinterpretation of any final rule, FDA make clear that tampons on the market are not misbranded and that no tampon can be considered to be misbranded for noncompliance with the final rule unless it is introduced into commerce after the rule's effective date. The other manufacturer continued to disagree that the failure to provide such absorbency information renders tampons misbranded.

In response to these comments, FDA reiterates that, as the agency tentatively concluded (53 FR 37250 at 37254), omission of uniform absorbency information does render tampons misbranded within the meaning of section 502 (a) and (f)(1) of the act. But, rather than act against individual tampons to remedy the deficiency, FDA has elected, consistent with its authority, to address the misbranding by requiring a uniform labeling system through rulemaking. As provided in § 801.403(h) of the final rule, any tampon that is not labeled as required by the final rule and that is initially introduced into interstate commerce after the effective date of the final rule is misbranded under sections 201(n) and 502 (a) and (f) of the act (21 U.S.C. 321(n) and 352 (a) and (f)). (The effective date of the final rule is discussed in section II E of this preamble.)

B. Approaches to Absorbency Labeling

4. FDA specifically requested comment (54 FR 25076 at 25081) on whether the use of fixed, nonoverlapping ranges would be inconsistent with the goal of enabling consumers to reduce their risk of TSS. Comments on this issue were received from consumer groups, consumers, and tampon manufacturers.

One consumer group continued to reject fixed, nonoverlapping ranges stating that a single number is necessary to adequately convey absorbency information to consumers. This comment suggested that the use of ranges would prevent women from being able to distinguish between tampon brands or styles at either the low or high end of a given absorbency range. It also noted that some styles of currently marketed tampons would have to be reformulated because their absorbency is on the boundary between ranges. The comment also urged that single numbers are more informative and clearer than ranges, that women are familiar with some manufacturers' current use of numbers, and that scientists have been using single numbers to designate the absorbency of tampons since 1981.

Most of the individual consumers favored the use of nonoverlapping ranges, as did three other consumer groups and all the manufacturers. These comments generally agreed with FDA's tentative conclusion (53 FR 37250 at 37260), or agreed with the statements on the issue in the reproposed rule (54 FR 25076 at 25080), that variations in tampon production and tampon absorbency testing make the use of ranges necessary; that the ranges chosen by FDA were appropriate and as narrow as possible given current production and testing; and that the benefit of truthful, nonmisleading, and accurate labeling outweighs the potential risks posed by the increased absorbency of some tampons that would result from product reformulation. Several individual consumers suggested reducing the number of ranges to avoid confusion and increase comprehension.

As stated in the preambles to the proposed rule (53 FR 37250 at 37260) and the reproposed rule (54 FR 25076 at 25080), the data show that a single numerical designation does not accurately represent the contents of a given box of tampons, and that the only truthful, accurate, and nonmisleading representation of the contents of a box can be that it contains tampons with absorbencies within a given range. Most of the comments agreed with FDA's interpretation of the data.

If future advances in technology across the industry allowed the production of tampons and the measurement of their absorbency such that there were only slight variations from an average absorbency, FDA would consider proposing amendments to this final rule.

Reducing the number of ranges could not be accomplished by simply eliminating one or more of them, because there is no basis for FDA to ban the use of any of the ranges, whether at the top or bottom end. The only way to reduce the number of ranges is to create ranges that are unnecessarily broad. FDA disagrees, therefore, with the recommendation that the ranges of absorbency be reduced below six.

5. FDA received many comments on whether to standardize a new set of terms or standardize the existing terms currently used by manufacturers, e.g., regular, super, and super plus.

One manufacturer and six individual consumers supported the reproposal requiring the use of new and standardized terms, but allowing the use of familiar and unstandardized terms. The manufacturer argued that the reproposed absorbency nomenclature was straightforward and clear, and objected to standardizing existing terms because it would have little impact on reinforcing absorbency information.

Four consumer groups, 4 manufacturers, 1 health professional organization, and 15 individual consumers strongly objected to the reproposal to allow the dual use of a new set of standardized terms with nonstandardized existing terms. These comments were unanimous in their view that such a dual system would result in consumer confusion and the failure of the reproposed rule to accomplish its intended goal of enabling consumers to compare, before purchase, the absorbency of one brand and style of tampons with the absorbency of other brands and styles. These comments differed, however, in their suggestions on how to eliminate the confusion that would result from the labeling scheme in the reproposal.

One consumer group, the health professional organization, and nine individual consumers stated that the new terms in the reproposed rule were acceptable, and that confusion would be eliminated if the use of existing terms were proscribed. Three consumer groups, four manufacturers (representing approximately 90 percent of the tampon market), and six individual consumers argued that the best approach was simply to standardize the existing terms that have been used for years and with which women are familiar. In addition, several comments suggested minor modifications of the new terms, if the new terms were retained in the final rule.

FDA has concluded, based on its own analysis, and on the preponderance of comments, which represent a large portion of the public that will be affected by this rule, that allowing any combination of standardized and nonstandardized absorbency terms will confuse rather than inform consumers, as a result of which the reproposed rule would not have achieved its stated public health purposes. Presented with two sets of terms on the same package,

consumers would likely continue to choose tampons based on the familiar terms, which would not be uniform throughout the tampon industry.

The agency rejects the option of using the new terms in the reproposal and proscribing the use of existing terms because it would fail to take advantage of consumer familiarity with existing terms. Moreover, it would be a more restrictive limitation on labeling than is necessary to serve the purpose of the final rule.

The agency agrees with the suggestion simply to standardize existing terms, without the addition of any new terms for the following reasons. This approach avoids any possible confusion; it is likely to be very easily understood by all consumers; is overwhelmingly the option most favored by consumers, who are the target audience for the information; it is the simplest to implement; and it is strengthened by and takes advantage of consumer familiarity with existing terms. Accordingly, the agency has revised reproposed § 801.430(e)(1) in the final rule to standardize the existing absorbency terms (junior, regular, super, and super plus) corresponding to the following four absorbency ranges: less than 6, 6 to 9, 9 to 12, and 12 to 15 grams of fluid, respectively, and to provide for no absorbency terms for the two absorbency ranges above 15 grams of fluid. Because absorbency terms, for the first time, will be valid indicators of absorbency across all tampon brands and styles, FDA believes that it is appropriate to require the word "absorbency" to accompany the existing terms, just as the reproposal would have required the word "absorbency" to accompany the new terms. Also, requiring the word "absorbency" on the package in conjunction with the absorbency term will alert consumers to the fact that the labeling has been changed.

The final rule does not include a corresponding term of absorbency for the ranges 15 to 18 grams or above 18 grams of fluid. FDA is unaware of any currently marketed tampon that absorbs more than 18 grams of fluid and also is unaware of any currently used, and therefore familiar, term of absorbency used to describe such a product. Any person who is required to register under section 510 of the act (21 U.S.C. 360) and 21 CFR part 807 of FDA's regulation and who intends to begin the introduction or delivery for introduction into interstate commerce of such a tampon for commercial distribution is required to submit a premarket notification to FDA in accordance with section 510(k) of the act and Subpart E of 21 CFR part 807 at least 90 days before making such introduction or delivery. Under § 807.87(e), a premarket notification for a device is to contain, among other things, labeling for the device. Based on such a submission for a tampon that absorbs more than 18 grams of fluid, the agency will determine whether the labeling is appropriate and does not misbrand or adulterate the tampon under section 501 or 502 of the act (21 U.S.C. 351 and 352) and whether the tampon requires premarket approval under section 515 of the act (21 U.S.C. 360e).

FDA is aware of one product in the 15 to 18-gram range that is currently labeled super plus. The manufacturer of this product will be required to lower the absorbency to continue to use the term super plus. All other manufacturers apply the term super plus to products with absorbencies in the 12 to 15-gram range. If the manufacturer using the term super plus for a product in the 15 to 18-gram range chose to keep this product at its current absorbency, FDA would review any term of absorbency proposed by the manufacturer. Because the final rule does not preclude the use of other labeling that is not false or misleading, the agency would consider the use of the absorbency range in § 801.430(e)(1) to be acceptable.

C. Absorbency Testing

6. Three manufacturers commented on the test method for determining tampon absorbency. One manufacturer recommended that the final rule permit manufacturers to use either the proposed or the reproposed method with appropriate technical adjustments that can be shown to be necessary to minimize error. Another manufacturer objected to the inclusion of a tensile strength requirement for the condom used in the test, arguing that there are no data showing that the results of the test are related to condom tensile strength and that ensuring that the tensile strength provision is met would be overly burdensome to tampon manufacturers. The third manufacturer objected to the provision in the reproposed rule that would have allowed alternative ways to reach the endpoint of the test (i.e., fluid either exits from the apparatus or appears in the folds of the condom below the tampon). The comment stated that this provision would create more interlaboratory error in the test method when some manufacturers select one alternative and some the other because, based on this manufacturer's preliminary data, the two endpoints could vary by as much as 0.5 grams of fluid.

The agency continues to recognize that individual manufacturers may wish to use an absorbency test method different from the test method specified in the final rule. Therefore, the agency has retained in the final rule a provision for a manufacturer to submit evidence, in the form of a citizen petition, demonstrating to the agency's satisfaction that the alternative method will yield test results that are equivalent to the results using the test method in the final rule. FDA believes, however, that allowing "technical adjustments" to the test method by individual manufacturers would likely lead to significant differences between the absorbency results obtained by different manufacturers. Neither the proposed nor reproposed rules would have permitted such adjustments and FDA has included no provisions in the final rule for manufacturers to make technical adjustments without FDA approval as described above. The agency does agree, however, that multiple endpoints could result in unnecessary variability in test results between manufacturers. Therefore, in response to the comments, and after reconsideration of the position taken in the reproposed rule, § 801.430(f)(2) is revised to state that the test should be terminated when the tampon is saturated and the first drop of fluid exits the apparatus.

FDA disagrees with the comment objecting to the inclusion of a condom tensile strength provision. FDA included this provision in repsonse to a comment on the proposed rule indicating that there was a need to specify the condom to be used. The earlier comment included information that identifying one brand of condom would not suffice because modifications in that brand made by the condom manufacturer would affect the test result. As condom manufacturers modify their products to respond to the market desire for condoms that are more resistant to breakage, it is possible that unnecessary variations could be introduced into the test method. For these reasons, FDA has concluded that it is necessary to specify the tensile strength of the condom used in the test method. FDA does not believe that this requirement would be overly burdensome. FDA's experience shows that tensile strengths greater than 30 Mega Pascals are associated with clearly thicker latex condoms, suggesting that tampon manufacturers may be able to use thickness in acceptance testing to ensure this tensile strength requirement is met. Alternatively, quality assurance data

provided by the condom supplier could be available to the tampon manufacturer as a possible means to comply with this provision.

7. Three consumer groups continued to urge FDA to adopt a 95/95 tolerance interval to provide the highest degree of assurance that tampons in fact fall within the specified ranges. Three manufacturers agreed that a 90/90 tolerance interval was acceptable, but expressed concern over a wording change in the reproposal that would have applied the tolerance interval to tampons within a package and not within a brand and type.

As stated in the preamble to the reproposed rule (54 FR 25076 at 25084), FDA has concluded that it is technically infeasible for manufacturers to comply with a requirement that there be a 95 percent probability that 95 percent of tampons fall within the labeled range, that it is technically feasible for all manufacturers to comply with a 90/90 tolerance interval, and that a 90/90 tolerance interval would provide a sufficiently high degree of assurance that tampons fall within the labeled range. In the absence of data to the contrary, the agency has not changed its conclusion. FDA does agree that an inappropriate wording change was made in the reproposed rule when the tolerance interval was applied to tampons in a package. The intent of the agency remains as stated in the proposed rule where the tolerance interval was applied to tampons within a brand or type, and, accordingly, has revised the final rule.

8. One manufacturer continued to posit that imprecision in the test method warranted applying the tolerance intervals to average absorbencies from small groups of tampons. In support of this position, the manufacturer submitted additional data comparing the absorbencies of two groups of tampons with the same average weight. One group, however, had a normally distributed narrow weight range (± 1 percent) and one group had a normally distributed wide weight range (± 8 percent). The average standard deviation for the syngyna values of tampons from the narrow weight range group was 0.4, and the average standard deviation from the wide weight range group was 0.66. The comment interpreted these data as confirming that the variation was due only to the test method for the narrow weight range group and the test method plus weight variation for the wide weight range group. Because of the test method variability, the comment concluded that it was appropriate to allow averaging of the absorbency values of small groups of tampons. Two consumer groups and one manufacturer agreed with FDA's conclusion that testing should be based on individual product unit values, rather than on averages.

FDA carefully evaluated the new data submitted in the comment and has concluded that the data do not demonstrate that there is such a large variability in the test method that it is necessary to apply tolerance intervals to average absorbencies. FDA believes that the data collection approach submitted with the comment, overlooks the contribution that all variables in the manufacturing process make to the final result. Thus, FDA concludes from the data that the standard deviation of 0.4 in the narrow weight group is the result of variations in the test method, fibers, and manufacturing; and that the standard deviation of 0.66 in the wide weight range group is the result of all of these variables plus weight. To find the variation attributable to the method exclusively would require a more detailed and carefully controlled experiment in which the several potential sources of variation in raw material and manufacturing were quantified and evaluated to determine their influence on the absorbency measurement.

D. Content and Location of Labeling

9. Four consumer groups and several individual consumers expressed concern that the use of the word "labeling" in reproposed § 801.430(d) would result in absorbency information being placed only in the package insert and not on the package label. One manufacturer suggested that the absorbency information be expanded to make specific reference to the link between tampon absorbency and the risk of TSS. Three consumer groups supported the language in the reproposal that would clearly identify in the labeling the practice of alternating tampon and sanitary pad use with reducing the risk of TSS.

The final rule (§ 801.430(e)(1)) requires that absorbency information shall be prominently and legibly placed on the package label of menstrual tampons. The absorbency information may not be placed only in a package insert. Section 801.430(e)(2) requires that the package label shall include an explanation of the ranges of absorbency and a description of how consumers can use a range of absorbency, and its corresponding absorbency term, to make comparisons of absorbency of tampons to allow selection of the tampon with the minimum absorbency needed to control menstrual flow in order to reduce the risk of contracting TSS.

10. Three manufacturers expressed concern that the prominence requirement in reproposed § 801.430(e)(2) would result in restrictions on generic names, brand names, and the like that were not intended in the reproposal. One consumer group requested clarification as to the meaning of prominent and conspicuous in reproposed § 801.430(e)(2). To ensure prominence, various comments suggested graphs/scales/guages; bold format, as in the Surgeon General's warning on cigarette packages; color-coding; and the use of dramatic labeling on cellophane wrappers.

Because FDA has decided in the final rule to require the standardization of existing terms instead of new terms, the language in reproposed § 801.430(e)(2) is removed from the final rule. Although FDA agrees that there are specific ways to ensure prominence of the labeling required in the final rule, the agency has concluded that there is no need to specify any single approach, thus providing flexibility to manufacturers.

11. Two consumer groups, two individual consumers, and one manufacturer commented on the need for ingredient labeling. The two consumer groups reiterated the support for ingredient labeling. The two individual consumers argued that it should not be necessary for an ingredient to be a health risk to justify ingredient labeling for tampons; materials should be disclosed so women can make an "intelligent choice," e.g., choose tampons with natural fibers. The manufacturer reiterated that manufacturers now voluntarily provide ingredient information, but agreed that FDA has insufficient legal basis for requiring it.

FDA tentatively concluded in the preamble to the reproposed rule (54 FR 25076 at 25085) that it does not have the authority under the act to require tampon manufacturers to list ingredient information on product labeling, unless such ingredient information were necessary for the safe and effective use of tampons. None of the comments favoring ingredient labeling cited, discussed, or submitted any data showing an association between any particular ingredient and any risk to health, including allergic reaction, sensitivity, or irritation, and FDA is unaware of any such data. Moreover, none of the comments provided any legal theory under which the agency could require ingredient labeling for tampons. Absent information indicating

that the disclosure of tampon ingredients on package labeling is necessary for the safe or effective use of the product, or that the omission of such information is material to the safe or effective use of the tampons, FDA has concluded that the act does not provide the agency with authority to require tampon manufacturers to list ingredient information on product labeling.

E. Effective Date

12. Two consumer groups supported a 6-month implementation date as the latest acceptable effective date. One manufacturer considered 6 months to be sufficient time for it to comply with the proposed rule. Three manufacturers continued to object to a 6-month effective date. These manufacturers claimed they would have difficulty meeting a 6-month effective date because they would have to make labeling changes and product design changes that would affect manufacturing, including machinery, and testing protocols. They also cited the unnecessary risk of having to scrap not only packaging but actual product in inventory. These comments suggested effective dates ranging from 9 months to 1 year. One individual consumer supported the view that 6 months was not enough time for manufacturers to design effective packaging to meet the new regulation.

As stated in the preamble to the reproposal, the agency believes that the basic testing methodology required by the final rule has been accepted by manufacturers, and that appropriate quality assurance programs have been in place since the device current good manufacturing practice (CGMP) regulations were promulgated in 1978 (21 CFR 820.20). Therefore, manufacturers are faced only with modification of existing quality assurance programs and not with creation of entirely new ones, and the need to develop and print new product labeling. Given the public health importance of tampon absorbency information, FDA believes that any time beyond 6 months is neither necessary nor appropriate for implementation of the provisions in § 801.430(e) (1) and (2), and (f) regarding absorbency ranges and testing. Based upon available information, FDA had proposed that any final rule become effective 6 months after the date the final rule is published in the **Federal Register**, because of the agency's belief that manufacturers would need this amount of time to implement the labeling changes required in § 801.430(e) (1) and (2). However, on September 29, 1989, the United States District Court for the District of Columbia ordered that the final tampon absorbency regulation become effective 4 months after October 30, 1989, the date by which the court had, by its previous order of August 29, 1989, directed that publication of the final rule occur. *Public Citizen Health Research Group* v. *Commissioner, FDA*, Civil Action No. 88–1492. Accordingly, the final rule is effective on March 1, 1990. Any menstrual tampon that is not labeled as required by the final rule and that is initially introduced or initially delivered for introduction into commerce after March 1, 1990, is misbranded under sections 201(n) and 502 (a) and (f) of the act.

The agency believes that manufacturers might want for some period of time to relate new labeling to the former product labeling. Therefore, the agency would consider it appropriate if a manufacturer, for up to 12 months after the effective date of the final rule, chose to include, for example, the information "formerly Brand X super" in the product labeling.

F. Vending Machines

13. Two consumer groups and 10 individual consumers argued that the reproposed rule would not ensure that a consumer had the necessary information about absorbency of vending machine products in order to make an informed choice as between, for example, a tampon or a sanitary pad. One manufacturer argued that absorbency labeling of vending machine tampons is neither practical nor necessary, since consumers must purchase whatever single product is available in a particular vending machine and do not have a choice.

Because FDA has revised the final rule to standardize existing terms, the agency reviewed the provision (§ 801.430(g)) in the reproposed rule that did not exempt tampons sold in vending machines from the provision of § 801.430(e)(4). FDA no longer believes this provision is necessary, and has revised the final rule accordingly. FDA finds no basis in the comments for concluding that requiring tampons sold in vending machines to comply with the final rule is necessary to protect the public health.

G. Public Citizen Health Research Group Petition

14. No comments were received that specifically addressed the August 20, 1987, citizen petition from the Health Research Group (HRG) (see 53 FR 37250 at 37252 and 37253). FDA believes that the final rule, requiring uniform absorbency testing and a standardized method of expressing absorbency, is both technically feasible and adequate to address the need for public health protection. The final rule enables women to compare absorbencies between brands and styles and to choose the lowest absorbency needed and, thus, reduce their risk of contracting TSS. To the extent that the final rule does not include provisions requested by HRG in its August 20, 1987, citizen petition, the agency is denying the petition.

H. Education

15. Three consumer groups and three individual consumers urged FDA to continue its public education efforts to inform users of the association between tampon absorbency and TSS risk. Specific suggestions included incorporating TSS education information into school curricula, using formats targeted to specific age groups and making public service announcements.

FDA agrees with the intent of these comments. FDA plans to employ a variety of educational approaches to provide updated information to new tampon users, higher risk groups for TSS such as young women and teenage girls, and the general public, and will consider the suggestions provided in the comments.

I. Miscellaneous

16. A comment from two consumer groups presented data on problems with the structural integrity of tampons and urged FDA to increase the priority for the development of a standard for tampon performance to include parameters such as biocompatibility, leachability of materials, anchor string strength, and smoothness and mechanical operation of the tampon inserter.

FDA will consider the new data submitted in the comment in its continuing revision of its priorities for development of mandatory standards for medical devices.

17. An individual consumer recommended against the use of metric measures, expressing the view that they are poorly understood and virtually meaningless to the general public.

The purpose of the determination of the fluid absorbed by a tampon is to provide a quantitative measure of absorbency that can be used in making interbrand comparisons. FDA does not believe that it is necessary to use English system units (ounces) to do that, and rejects the recommendation.

18. FDA also received suggestions for further changes in tampon labeling. For example, one comment recommended that the agency require

recommendations and warnings for women with unusually heavy menstrual periods. Another comment recommended establishing a minimum absorbency to protect consumers from fraudulent products and a maximum absorbency to safeguard the health of consumers.

FDA believes that the warnings about the link between TSS and tampon absorbency, and the admonition to reduce that risk by alternating tampon use with menstrual pads, will provide all women, including those with unusually heavy periods, the information they need to take action to reduce the risk of TSS. The agency does not believe that there is a basis for establishing either a minimum absorbency or a maximum absorbency for tampon products, and, therefore, rejects that comment.

III. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Economic Impact

As stated in the preambles to the proposed and reproposed rules, FDA has assessed the economic consequences of the final rule in accordance with the criteria in section 1(b) of Executive Order 12291 and found that the rule is not a major rule under the Executive Order. No comments were received in response to the reproposed rule relating to FDA's assessment. As in the reproposed rule, FDA estimates that the final rule will impose direct costs of $75,000 on each tampon manufacturer. Therefore, the agency continues to conclude that the rule is not a major rule under the Executive Order. The agency also has considered the effect that the final rule will have on small entities including small businesses. The agency believes that only one of the affected manufacturers meets the definition of a small entity under the Regulatory Flexibility Act (Pub. L. 96–354), and no comments were submitted on the matter. Therefore, FDA certifies under the Regulatory Flexibility Act that the final rule will not have a significant economic impact on a substantial number of small entities. A further description of these new costs and the methods for estimating them can be found in the revised threshold assessment on file with the Dockets Management Branch, Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

V. Paperwork Reduction

This final rule (§ 801.430 (e) and (f)) contains information collection requirements that were submitted for review and approval to the Director, Office of Management and Budget (OMB) as required by section 3507 of the Paperwork Reduction Act of 1980. The requirements were approved and assigned OMB control number 0910–0257.

List of Subjects in 21 CFR Part 801

Incorporation by reference, Labeling, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, 21 CFR part 801 is amended as follows:

PART 801—LABELING

1. The authority citation for 21 CFR part 801 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 507, 519, 520, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 357, 360i, 360j, 371, 374).

2. Section 801.430 is amended by revising paragraph (b), the introductory text of paragraph (d), and paragraphs (d)(2), (3), and (4); by redesignating paragraphs (e) and (f) as paragraphs (g) and (h), respectively, and revising them; and by adding new paragraphs (e) and (f) to read follows:

§ 801.430 User labeling for menstrual tampons.

* * * * *

(b) Data show that toxic shock syndrome (TSS), a rare but serious and sometimes fatal disease, is associated with the use of menstrual tampons. To protect the public and to minimize the serious adverse effects of TSS, menstrual tampons shall be labeled as set forth in paragraphs (c), (d), and (e) of this section and tested for absorbency as set forth in paragraph (f) of this section.

* * * * *

(d) The labeling of menstrual tampons shall contain the following consumer information prominently and legibly, in such terms as to render the information likely to be read and understood by the ordinary individual under customary conditions of purchase and use:

* * * * *

(2) The risk of TSS to all women using tampons during their menstrual period, especially the reported higher risks to women under 30 years of age and teenage girls, the estimated incidence of TSS of 1 to 17 per 100,000 menstruating women and girls per year, and the risk of death from contracting TSS;

(3) The advisability of using tampons with the minimum absorbency needed to control menstrual flow in order to reduce the risk of contracting TSS;

(4) Avoiding the risk of getting tampon-associated TSS by not using tampons, and reducing the risk of getting TSS by alternating tampon use with sanitary napkin use during menstrual periods; and

* * * * *

(e) The statements required by paragraph (e) of this section shall be prominently and legibly placed on the package label of menstrual tampons in conformance with section 502(c) of the Federal Food, Drug, and Cosmetic Act (the act) (unless the menstrual tampons are exempt under paragraph (g) of this section).

(1) Menstrual tampon package labels shall bear one of the following absorbency terms representing the absorbency of the production run, lot, or batch as measured by the test described in paragraph (f)(2) of this section;

Ranges of absorbency in grams [1]	Corresponding term of absorbency
6 and under	Junior absorbency.
6 to 9	Regular absorbency.
9 to 12	Super absorbency.
12 to 15	Super plus absorbency.
15 to 18	None.
above 18	None.

[1] These ranges are defined, respectively, as follows: less than or equal to 6 grams; greater than 6 grams up to and including 9 grams; greater than 9 grams up to and including 12 grams; greater than 12 grams up to and including 15 grams; greater than 15 grams up to and including 18 grams; and greater than 18 grams.

(2) The package label shall include an explanation of the ranges of absorbency and a description of how consumers can use a range of absorbency, and its corresponding absorbency term, to make comparisons of absorbency of tampons to allow selection of the tampons with the minimum absorbency needed to control menstrual flow in order to reduce the risk of contracting TSS.

(f) A manufacturer shall measure the absorbency of individual tampons using the test method specified in paragraph (f)(2) of this section and calculate the mean absorbency of a production run, lot, or batch by rounding to the nearest 0.1 gram.

(1) A manufacturer shall design and implement a sampling plan that includes collection of probability samples of adequate size to yield consistent tolerance intervals such that the probability is 90 percent that at least 90 percent of the absorbencies of individual tampons within a brand and

type are within the range of absorbency stated on the package label.

(2) In the absorbency test, an unlubricated condom, with tensile strength between 17 Mega Pascals (MPa) and 30 MPa, as measured according to the procedure in the American Society for Testing and Materials (ASTM), D 3492–83, "Standard Specification for Rubber Contraceptives (Condoms)"[1] for determining tensile strength, which is incorporated by reference in accordance with 5 U.S.C. 552(a), is attached to the large end of a glass chamber with a rubber band (see Figure 1) and pushed through the small end of the chamber using a smooth, finished rod. The condom is pulled through until all slack is removed. The tip of the condom is cut off and the remaining end of the condom is stretched over the end of the tube and secured with a rubber band. A preweighed (to the nearest 0.01 gram) tampon is placed within the condom membrane so that the center of gravity of the tampon is at the center of the chamber. An infusion needle (14 gauge) is inserted through the septum created by the condom tip until it contacts the end of the tampon. The outer chamber is filled with water pumped from a temperature-controlled waterbath to maintain the average temperature at 27±1 °C. The water returns to the waterbath as shown in Figure 2.

Syngyna fluid (10 grams sodium chloride, 0.5 gram Certified Reagent Acid Fuchsin, 1,000 milliliters distilled water) is then pumped through the infusion needle at a rate of 50 milliliters per hour. The test shall be terminated when the tampon is saturated and the first drop of fluid exits the apparatus. (The test result shall be discarded if fluid is detected in the folds of the condom before the tampon is saturated). The water is then drained and the tampon is removed and immediately weighed to the nearest 0.01 gram. The absorbency of the tampon is determined by subtracting its dry weight from this value. The condom shall be replaced after 10 tests or at the end of the day during which the condom is used in testing, whichever occurs first.

BILLING CODE 4160-01-M

[1] Copies of the standard are available from the American Society for Testing and Materials, 1916 Race St., Philadelphia, PA 19103, or available for inspection at the Office of the Federal Register, 1100 L St., NW., Washington, DC.

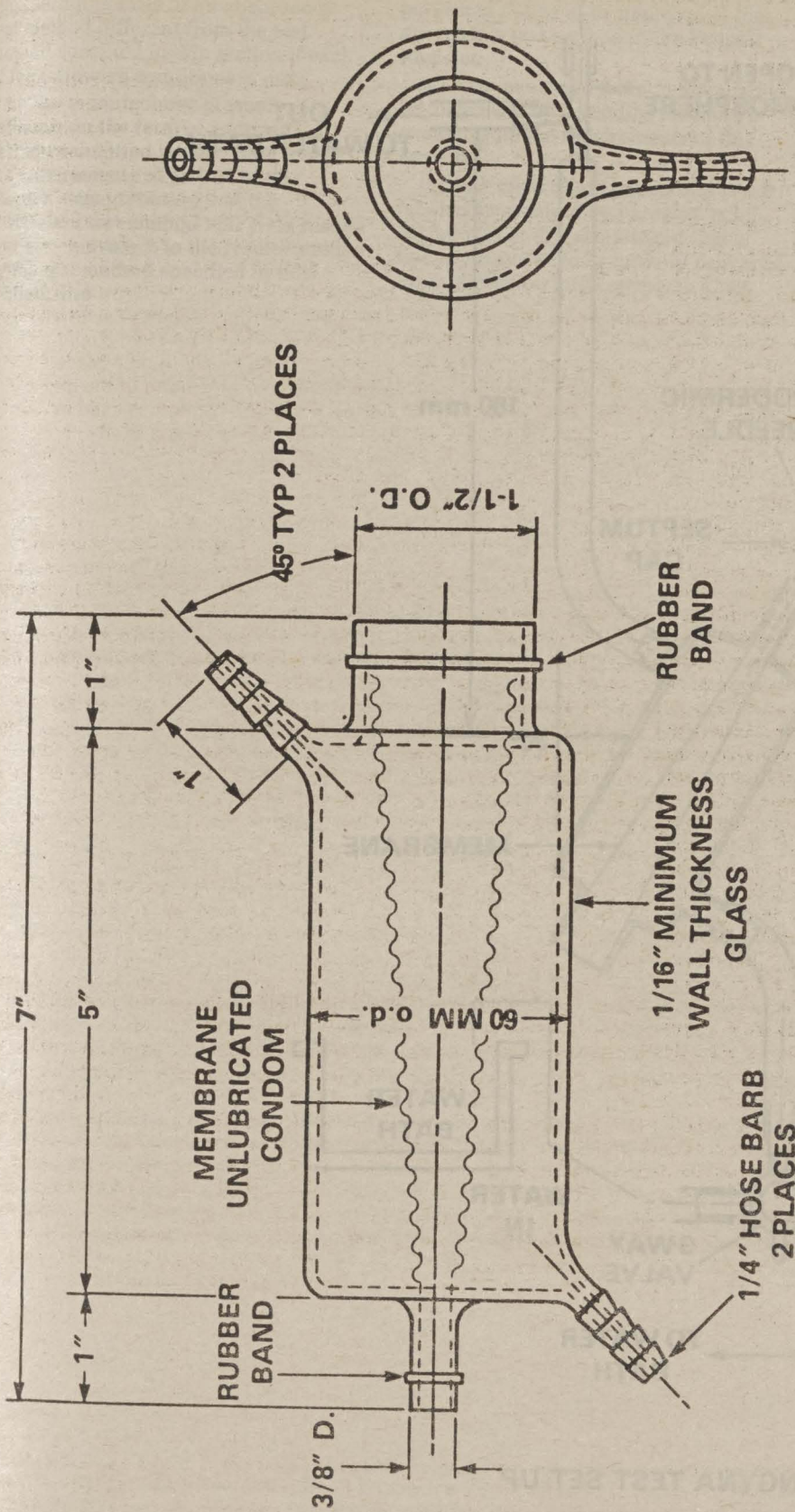

FIGURE 1 – SYNGYNA TEST CHAMBER

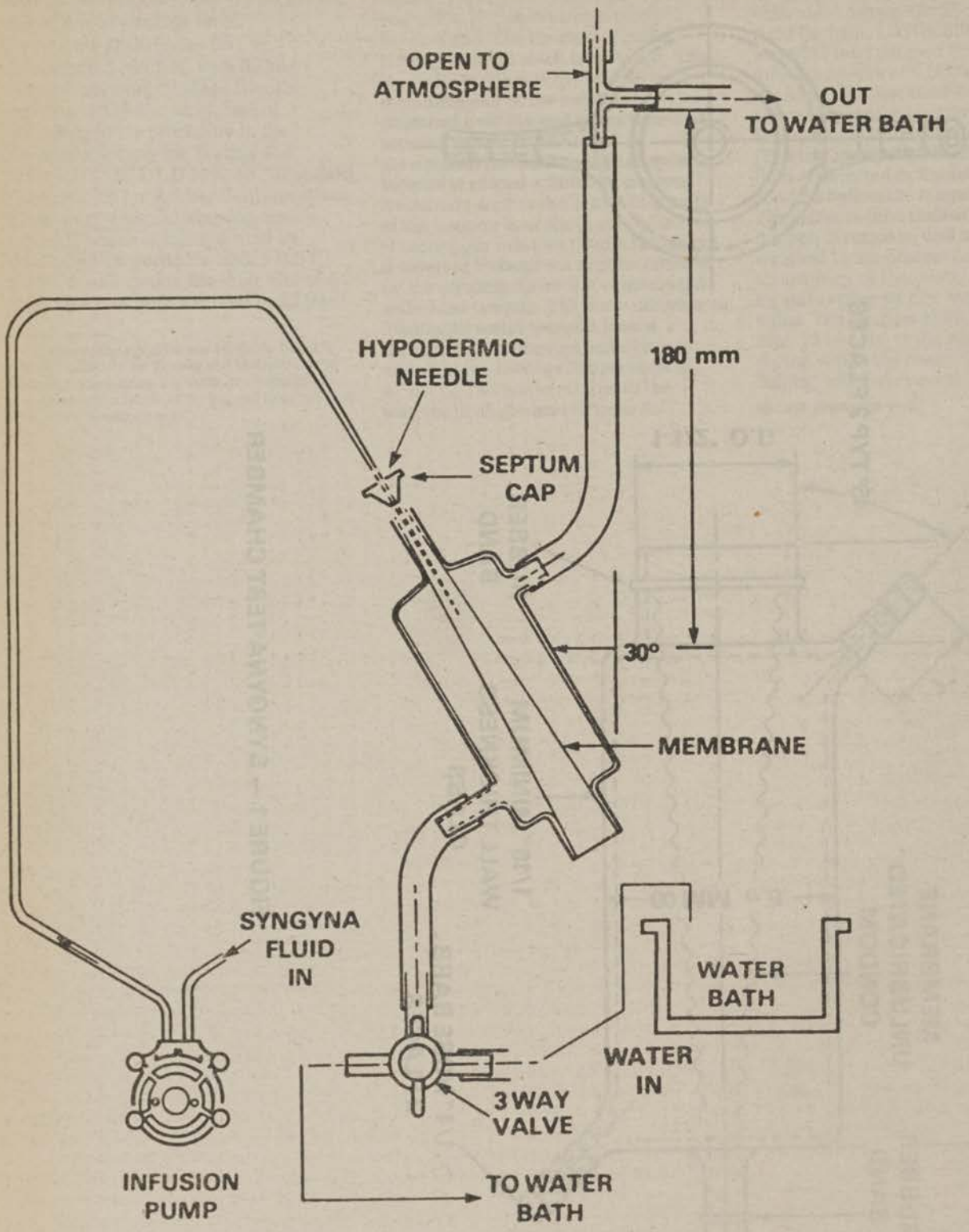

FIGURE 2—SYNGYNA TEST SET-UP

BILLING CODE 4160-01-C

(3) The Food and Drug Administration may permit the use of an absorbency test method different from the test method specified in this section if each of the following conditions is met:

(i) The manufacturer presents evidence, in the form of a citizen petition submitted in accordance with the requirements of § 10.30 of this chapter, demonstrating that the alternative test method will yield results that are equivalent to the results yielded by the test method specified in this section; and

(ii) FDA approves the method and has published notice of its approval of the alternative test method in the **Federal Register.**

(g) Any menstrual tampon intended to be dispensed by a vending machine is exempt from the requirements of this section.

(h) Any menstrual tampon that is not labeled as required by paragraphs (c), (d), and (e) of this section and that is initially introduced or initially delivered for introduction into commerce after March 1, 1990, is misbranded under sections 201(n), 502 (a) and (f) of the act.

(Information collection requirements contained in paragraphs (e) and (f) were approved by the Office of Management and Budget under control number 0910–0257)

Dated: October 17, 1989.

James S. Benson,

Acting Deputy Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

[FR Doc. 89–25221 Filed 10–23–89; 2:49 pm]

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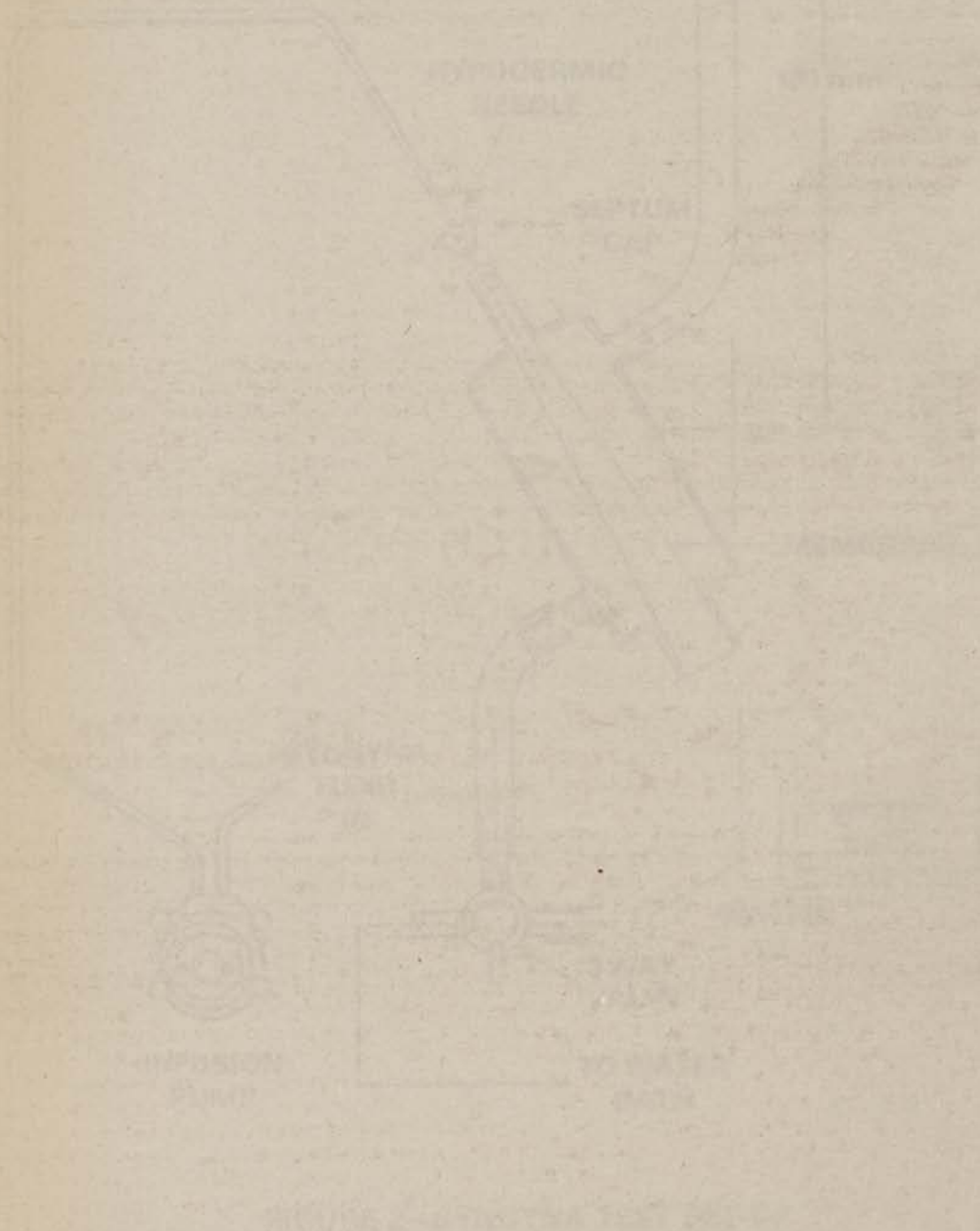

federal register

Thursday
October 26, 1989

Part V

Environmental Protection Agency

40 CFR Part 300

National Priorities List for Uncontrolled Hazardous Waste Sites; Proposed Update No. 10; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[FRL 3675-2]

National Priorities List for Uncontrolled Hazardous Waste Sites; Proposed Update No. 10

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency ("EPA") is proposing the tenth major update to the National Priorities List ("NPL"). The NPL is Appendix B to the National Oil and Hazardous Substances Pollution Contingency Plan ("NCP"), which was promulgated on July 16, 1982, pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 ("CERCLA"). CERCLA has since been amended by the Superfund Amendments and Reauthorization Act of 1986 ("SARA") and is implemented by Executive Order 12580 (52 FR 2923, January 29, 1987). CERCLA requires that the NCP include a list of national priorities among the known releases or threatened releases of hazardous substances, pollutants, or contaminants throughout the United States, and that the list be revised at least annually. The NPL, initially promulgated on September 8, 1983 (48 FR 40658), constitutes this list.

This update proposes to add 25 new sites to the NPL, including 2 Federal facility sites. These sites are being proposed because they meet the eligibility requirements and listing policies of the NPL. This notice provides the public with an opportunity to comment on placing these sites on the NPL.

This proposed rule brings the number of proposed NPL sites to 238, 65 of them in the Federal section; 981 sites are on the final NPL, 52 of them in the Federal section. Final and proposed sites now total 1,219.

DATES: Comments must be submitted on or before December 26, 1989.

ADDRESSES: Comments should be mailed, in triplicate, to Larry Reed, Acting Director, Hazardous Site Evaluation Division (Attn: NPL Staff), Office of Emergency and Remedial Response (OS-230), U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460. Addresses for the Headquarters and Regional dockets are provided below. For further details on what these dockets contain, see the "Public Comment Period" in section I of the **SUPPLEMENTARY INFORMATION** portion of this preamble.

Tina Maragousis, Headquarters, U.S. EPA CERCLA Docket Office, Waterside Mall, 401 M Street SW., Washington, DC 20460, 202/382-3046.

Evo Cunha, Region 1, U.S. EPA Waste Management Records Center, HES-CAN 6, J.F. Kennedy Federal Building, Boston, MA 02203, 617/565-3300.

U.S. EPA, Region 2, Document Control Center, Superfund Docket, 26 Federal Plaza, 7th Floor, Room 740, New York, NY 10278, Latchmin Serrano, 212/264-5540, Ophelia Brown, 212/264-1154.

Diane McCreary, Region 3, U.S. EPA Library, 5th Floor, 841 Chestnut Building, 9th & Chestnut Streets, Philadelphia, PA 19107, 215/597-0580.

Gayle Alston, Region 4, U.S. EPA Library, Room G-6, 345 Courtland Street NE., Atlanta, GA 30365, 404/347-4216.

Cathy Freeman, Region 5, U.S. EPA, 5 HS-12, 230 South Dearborn Street, Chicago, IL 60604, 312/886-6214.

Deborah Vaughn-Wright, Region 6, U.S. EPA, 1445 Ross Avenue, Mail Code 6H-MA, Dallas, TX 75202-2733, 214/655-6740.

Brenda Ward, Region 7, U.S. EPA Library, 726 Minnesota Avenue, Kansas City, KS 66101, 913/236-2828.

Dolores Eddy, Region 8, U.S. EPA Library, 999 19th Street, Suite 500, Denver, CO 80202-2405, 303/293-1444.

Linda Sunnen, Region 9, U.S. EPA Library, 6th Floor, 215 Fremont Street, San Francisco, CA 94105, 415/974-8082.

David Bennett, Region 10, U.S. EPA, 9th Floor, 1200 6th Avenue, Mail Stop HW-093, Seattle, WA 98101, 206/442-2103.

FOR FURTHER INFORMATION CONTACT: Martha Otto, Hazardous Site Evaluation Division, Office of Emergency and Remedial Response (OS-230), U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460, or the Superfund Hotline, Phone (800) 424-9346 (382-3000 in the Washington, DC, metropolitan area).

SUPPLEMENTARY INFORMATION:

Table of Contents:

I. Introduction

Background

In 1980, Congress enacted the Comprehensive Environmental Response, Compensation, and Liability Act, 42 U.S.C. sections 9601-9657 ("CERCLA" or the "Act") in response to the dangers of uncontrolled or abandoned hazardous waste sites. CERCLA was amended on October 17, 1986, by the Superfund Amendments and Reauthorization Act ("SARA"), Public Law No. 99-499, stat. 1613 *et seq.* To implement CERCLA, the Environmental Protection Agency ("EPA" or "the Agency") promulgated the revised National Oil and Hazardous Substances Pollution Contingency Plan ("NCP"), 40 CFR Part 300, on July 16, 1982 (47 FR 31180), pursuant to CERCLA section 105 and Executive Order 12316 (46 FR 42237, August 20, 1981). The NCP, further revised by EPA on September 16, 1985 (50 FR 37624) and November 20, 1985 (50 FR 47912), sets forth guidelines and procedures needed to respond under CERCLA to releases and threatened releases of hazardous substances, pollutants, or contaminants. On December 21, 1988 (53 FR 51394), EPA proposed revisions to the NCP in response to SARA.

Section 105(a)(8)(A) of CERCLA, as amended by SARA, requires that the NCP include "criteria for determining priorities among releases or threatened releases throughout the United States for the purpose of taking remedial action and, to the extent practicable, take into account the potential urgency of such action for the purpose of taking removal action." Removal action involves cleanup or other actions that are taken in response to releases or threats of releases on a short-term or temporary basis (CERCLA section 101(23)). Remedial action tends to be long-term in nature and involves response actions that are consistent with a permanent remedy for a release (CERCLA section 101(24)). Criteria for determining priorities for possible remedial actions financed by the Trust Fund established under CERCLA are included in the Hazard Ranking System ("HRS"), which EPA promulgated as Appendix A of the NCP (47 FR 31219, July 16, 1982).

On December 23, 1988 (53 FR 51962), EPA proposed revisions to the HRS in response to CERCLA section 105(c), added by SARA. EPA intends to issue the revised HRS as soon as possible. However, until EPA has reviewed public comments and the proposed revisions have been put into effect, EPA will continue to propose and promulgate sites using the current HRS, in accordance with CERCLA section 105(c)(1) and Congressional intent, as explained in 54 FR 13299 (March 31, 1989).

Based in large part on the HRS criterion, and pursuant to section 105(a)(8)(B) of CERCLA, as amended by SARA, EPA prepared a list of national priorities among the known releases or threatened releases of hazardous substances, pollutants, or contaminants throughout the United States. The list,

which is Appendix B of the NCP, is the National Priorities List ("NPL"). Section 105(a)(8)(B) also requires that the NPL be revised at least annually. A site can undergo CERCLA-financed remedial action only after it is placed on the NPL, as provided in the NCP at 40 CFR 300.66(c)(2) and 300.68(a).

An original NPL of 406 sites was promulgated on September 8, 1983 (48 FR 40658). The NPL has been expanded since then, most recently on October 4, 1989 (54 FR 41000/41015). The Agency also has published a number of proposed rulemakings to add sites to the NPL, most recently on August 16, 1989 (54 FR 33846) and Update #9 on July 14, 1989 (54 FR 29820).

EPA may delete sites from the NPL where no further response is appropriate, as explained in the NCP at 40 CFR 300.66(c)(7). To date, the Agency has deleted 28 sites from the final NPL, most recently on September 22, 1989 (54 FR 38994), when Cecil Lindsay, Newport, Arkansas, was deleted.

This notice proposes to add 25 sites to the NPL, including 2 Federal facility sites. Adding these 25 sites to the 213 sites previously proposed brings the total number of proposed sites to 238, 65 of them in the Federal section. The final NPL contains 981 sites, including 52 sites in the Federal section. Final and proposed sites now total 1,219.

EPA is proposing to include on the NPL sites at which there are or have been releases or threatened releases of hazardous substances, pollutants, or contaminants. The discussion below may refer to "releases or threatened releases" simply as "releases," "facilities," or "sites."

Public Comment Period

This **Federal Register** notice opens the formal 60-day comment period for NPL Update #10. Comments may be mailed to Larry Reed, Acting Director, Hazardous Site Evaluation Division (Attn: NPL staff), Office of Emergency and Remedial Response (OS-230), U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460.

The Headquarters and Regional public dockets for the NPL (see **ADDRESSES** portion of this notice) contain documents relating to the scoring of these proposed sites. The dockets are available for viewing, by appointment only, after the appearance of this notice. The hours of operation for the Headquarters docket are from 9:00 a.m. to 4:00 p.m., Monday through Friday excluding Federal holidays. Please contact individual Regional dockets for hours.

The Headquarters docket for NPL Update #10 contains HRS score sheets for each proposed site, a Documentation Record for each site describing the information used to compute the score, a list of documents referenced in the Documentation Record, and pertinent information for any site affected by statutory requirements and listing policies.

Each Regional docket includes all information available in the Headquarters docket for sites in that Region, as well as the actual reference documents, which contain the data EPA relied upon in calculating or evaluating the HRS scores for sites in that Region. These reference documents are available only in the Regional dockets. They may be viewed, by appointment only, in the appropriate Regional Docket or Superfund Branch office. Requests for copies may be directed to the appropriate Regional docket or Superfund Branch.

An informal written request, rather than a formal request, should be the ordinary procedure for obtaining copies of any of these documents.

EPA considers all comments received during the formal comment period. During the comment period, comments are available to the public only in the Headquarters docket. A complete set of comments pertaining to sites in a particular EPA Region will be available for viewing in the Regional docket approximately one week after the formal comment period closes. Comments received after the comment period closes will be available in the Headquarters docket and in the appropriate Regional Office docket on an "as received" basis. An informal written request, rather than a formal request, should be the ordinary procedure for obtaining copies of any comments. After considering the relevant comments received during the comment period, EPA will add to the NPL all proposed sites that meet EPA's requirements.

EPA will read all comments received on these sites, including late comments, i.e., comments postmarked after the last day of the comment period. In earlier NPL rulemakings, EPA has endeavored to respond even to late comments. However, given the need to make final decisions on all currently proposed sites prior to the date that the revised HRS takes effect, it is unlikely that EPA will be able to respond to all late comments received for sites in this proposed rule. *See* 54 FR 41021 (October 4, 1989).

Early Comments

In certain instances, interested parties have written to EPA concerning sites that were not at that time proposed to the NPL. If those sites are later proposed to the NPL, parties should review their earlier concerns and, if they still consider them appropriate, resubmit those concerns for consideration during the formal comment period. Site-specific correspondence received prior to proposal generally will not be included in the docket.

Comments Lacking Specificity

EPA anticipates that some comments will consist of or include additional studies or supporting documentation, e.g., hydrogeology reports, lab data, and previous site studies. Where commenters do not indicate what specific scoring issues the supporting documentation addresses, or what they want EPA to evaluate in the supporting documentation, EPA can only attempt to respond to such documents as best it can. Any commenter submitting additional documentation should indicate what specific points in that documentation that EPA should consider. As the U.S. Court of Appeals for the District of Columbia Circuit noted in *Northside Sanitary Landfill* v. *Thomas & EPA*, 849 F. 2d 1516, 1520 (D.C. Cir. 1988), *cert. denied*, 109 S. Ct. 1528 (1989), during notice-and-comment rulemaking a commenter must explain with some specificity how any documents submitted are relevant to issues in the rulemaking.

II. Purpose and Implementation of the NPL

Purpose

The primary purpose of the NPL is stated in the legislative history of CERCLA (Report of the Committee on Environment and Public Works, Senate Report No. 96-848, 96th Cong., 2d Sess. 60 (1980)):

> The priority lists serve primarily informational purposes, identifying for the States and the public those facilities and sites or other releases which appear to warrant remedial actions. Inclusion of a facility or site on the list does not in itself reflect a judgment of the activities of its owner or operator, it does not require those persons to undertake any action, nor does it assign liability to any person. Subsequent government action in the form of remedial actions or enforcement actions will be necessary in order to do so, and these actions will be attended by all appropriate procedural safeguards.

The purpose of the NPL, therefore, is primarily to serve as an informational and management tool. The initial identification of a site for the NPL is intended primarily to guide EPA in determining which sites warrant further investigation to assess the nature and extent of the public health and environmental risks associated with the

site and to determine what CERCLA-financed remedial action(s), if any, may be appropriate. The NPL also serves to notify the public of sites that EPA believes warrant further investigation.

Federal facility sites are eligible for the NPL purusant to the NCP at 40 CFR 300.66(c)(2). However, section 111(e)(3) of CERCLA, as amended by SARA, limits the expenditure of CERCLA monies at Federally-owned facilities. Federal facility sites also are subject to the requirements of CERCLA section 120, added by SARA.

Implementation

EPA has limited, by regulation, the expenditure of Trust Fund monies for remedial actions to those sites that have been placed on the final NPL, as outlined in the NCP at 40 CFR 300.66(c)(2) and 300.68(a). However, EPA may take enforcement actions under CERCLA or other applicable statutes against responsible parties regardless of whether the site is on the NPL, although, as a practical matter, the focus of EPA's CERCLA enforcement actions has been and will continue to be on NPL sites. Similarly, in the case of CERCLA removal actions, EPA has the authority to act at any site, whether listed or not, that meets the criteria of the NCP at 40 CFR 300.65–67.

EPA's policy is to pursue cleanup of NPL sites using the appropriate response and/or enforcement actions available to the Agency, including authorities other than CERCLA. Listing a site will serve as notice to any potentially responsible party that the Agency may initiate CERCLA-financed remedial action. The Agency will decide on a site-by-site basis whether to take enforcement or other action under CERCLA or other authorities, proceed directly with CERCLA-financed response actions and seek to recover response costs after cleanup, or do both. To the extent feasible, once sites are on the NPL, EPA will determine high-priority candidates for Superfund-financed response action and/or enforcement action through both State and Federal initiatives. These determinations will take into account which approach is more likely to most expeditiously accomplish cleanup of the site while using CERCLA's limited resources as efficiently as possible.

Remedial response actions will not necessarily be funded in the same order as a site's ranking on the NPL. Although most sites are listed in the order of their HRS scores, the Agency has recognized that the information collected to develop HRS scores is not sufficient in itself to determine either the extent of contamination or the appropriate response for a particular site. EPA relies on further, more detailed studies in the Remedial Investigation/Feasibility Study (RI/FS) to address these concerns.

The RI/FS determines the nature and extent of the threat presented by the contamination (40 CFR 300.68(d)). It also takes into account the amount of contaminants in the environment, the risk to affected populations and environment, the cost to correct problems at the site, and the response actions that have been taken by potentially responsible parties to others. Decisions on the type and extent of action to be taken at these sites are made in accordance with the criteria contained in Subpart F of the NCP. After conducting these additional studies, EPA may conclude that it is not desirable to initiate a CERCLA remedial action at some sites on the NPL because of more pressing needs at other sites, or because a private party cleanup is already underway pursuant to an enforcement action. Given the limited resources available in the Trust Fund, the Agency must balance carefully the relative needs for response at the numerous sites it has studied.

RI/FS at Proposed Sites. An RI/FS can be performed at proposed sites (or even non-NPL sites) pursuant to the Agency's removal authority under CERCLA, as outlined in the NCP at 40 CFR 300.68(a)(1). (Section 101(23) of CERCLA defines "remove" or "removal" to include "such actions as may be necessary to monitor, assess and evaluate the release or threat of release * * *." The definition of "removal" also includes "action taken under section 104(b) of this Act * * *," which authorizes the Agency to perform studies, investigations, and other information-gathering activities.)

Although an RI/FS generally is conducted at a site after the site has been placed on the NPL, in a number of circumstances the Agency elects to conduct an RI/FS at a proposed NPL site in preparation for a possible CERCLA-financed remedial action, such as when the Agency believes that a delay may create unnecessary risks to human health or the environment. In addition, the Agency may conduct an RI/FS to assist in determining whether to conduct a removal or enforcement action at a site.

Facility (Site) Boundaries. Listing on the NPL represents a determination that a "release" or threat of release has occurred, and needs to be evaluated under CERCLA. Although the HRS scoring package describes the release, it does not define fixed geographic boundaries for the site. The description of the release at the time of scoring is merely preliminary, and will need to be refined as more information is developed, as during the RI/FS; the NPL site, for the purposes of response action, will include the entire area where contaminants are found to have been placed or come to be located, as provided in CERCLA section 101(9), even if that area extends beyond that described in the HRS package. *See* 54 FR 13298 (March 31, 1989).

Because the NPL listing is not intended to, and does not, define the geographic extent of the release, it is not meaningful to consider "delisting" allegedly uncontaminated portions of a site from the NPL. However, the RI/FS or Record of Decision (ROD) at a site may offer a useful indication to the public of the areas at which the Agency is considering taking response action, based on information known at that time. *See* 54 FR 41015 (October 4, 1989).

III. NPL Update Process

There are three mechanisms for placing sites on the NPL. The principal mechanism is the application of the HRS. The HRS serves as a screening device to evaluate the relative potential of uncontrolled hazardous substances to cause human health or safety problems, or ecological or environmental damage. The HRS score is calculated by estimating risks presented in three potential "pathways" of human or environmental exposure: Ground water, surface water, and air. Within each pathway of exposure, the HRS considers three categories of factors that are designed to encompass most aspects of the likelihood of exposure to a hazardous substance through a release and the magnitude or degree of harm from such exposure: (1) Factors that indicate the presence or likelihood of a release to the environment; (2) factors that indicate the nature and quantity of the substances presenting the potential threat; and (3) factors that indicate the human or environmental "targets" potentially at risk from the site. Factors within each of these three categories are assigned a numerical value according to a set scale. Once numerical values are computed for each factor, the HRS uses mathematical formulas that reflect the relative importance and interrelationships of the various factors to arrive at a final site score on a scale of 0 to 100. The resultant HRS score represents an estimate of the relative "probability and magnitude of harm to the human population or sensitive environment from exposure to hazardous substances as a result of the contamination of ground water, surface water, or air" (47 FR 31180, July 16, 1982). Those sites that score 28.50 or

greater on the HRS are eligible for the NPL.

Under the second mechanism for adding sites to the NPL, each State may designate a single site as its top priority, regardless of the HRS score. This mechanism is provided by section 105(a)(8)(B) of CERCLA, as amended by SARA, which requires that, to the extent practicable, the NPL include within the 100 highest priorities, one facility designated by each State representing the greatest danger to public health, welfare, or the environment among known facilities in the State.

The third mechanism for listing, included in the NCP at 40 CFR 300.66(b)(4) (50 FR 37624, September 16, 1985), has been used only in rare instances. It allows certain sites with HRS scores below 28.50 to be eligible for the NPL if all of the following occur:

- The Agency for Toxic Substances and Disease Registry of the U.S. Department of Health and Human Services has issued a health advisory that recommends dissociation of individuals from the release.
- EPA determines that the release poses a significant threat to public health.
- EPA anticipates that it will be more cost-effective to use its remedial authority than to use its removal authority to respond to the release.

States have the primary responsibility for identifying non-Federal sites, computing HRS scores, and submitting candidate sites to the EPA Regional Offices. EPA Regional Offices conduct a quality control review of the States' candidate sites, and may assist in investigating, sampling, monitoring, and scoring sites. Regional Offices also may consider candidate sites in addition to those submitted by States. EPA Headquarters conducts further quality assurance audits to ensure accuracy and consistency among the various EPA and State offices participating in the scoring. The Agency then proposes the sites that meet one of the three criteria for listing (and EPA's listing policies) and solicits public comment on the proposal. Based on these comments and further review by EPA, the Agency determines final HRS scores and places those sites that still qualify on the NPL.

IV. Statutory Requirements and Listing Policies

CERCLA restricts EPA's authority to respond to certain categories of releases of hazardous substances, pollutants, or contaminants by expressly excluding some substances, such as petroleum, from the response program. In addition, CERCLA section 105(a)(8)(B) directs EPA to list priority sites "among" the known releases or threatened releases of hazardous substances, pollutants, or contaminants, and section 105(a)(8)(A) directs EPA to consider certain enumerated and "other appropriate" factors in doing so. Thus, as a matter of policy, EPA has the discretion not to use CERCLA to respond to certain types of releases. For example, EPA has chosen not to list sites that result from contamination associated with facilities licensed by the Nuclear Regulatory Commission (NRC), on the grounds that the NRC has the authority and expertise to clean up releases from those facilities (48 FR 40661, September 8, 1983). Where other authorities exist, placing the site on the NPL for possible remedial action under CERCLA may not be appropriate. Therefore, EPA has chosen to defer certain types of sites from the NPL even though CERCLA may provide authority to respond. If, however, the Agency later determines that sites not listed as a matter of policy are not being properly responded to, the Agency may place them on the NPL. The listing policies and the statutory requirement of particular relevance to this proposed rule cover Federal facility sites, sites with "special study wastes," and mining waste sites. They are discussed below. These and other listing policies and statutory requirements have been explained in previous rulemakings, the latest being March 31, 1989 (54 FR 13296) and October 4, 1989 (54 FR 41000).

Releases From Federal Facility Sites

On March 13, 1989 (54 FR 10520), the Agency announced a policy for listing Federal facility sites on the NPL if they meet the prescribed eligibility criteria (e.g., and HRS score of 28.50 or greater), even if the Federal facility also is subject to the corrective action authorities of Subtitle C of the Resource Conservation and Recovery Act (RCRA). In that way, cleanup, if appropriate, could be effected at those sites under CERCLA.

Federal facility sites are placed in a separate section of the NPL. In this rule, the Agency is proposing to add 2 Federal facility sites to the NPL, bringing the total number of proposed Federal facility sites to 65.

Releases of Special Study Wastes

Section 105(g) of CERCLA, as amended by SARA, requires EPA to consider additional information before sites involving RCRA "special study wastes" can be proposed for the NPL (until revisions to the HRS are effected). Section 105(g) applies to sites that (1) were not on or proposed for the NPL as of October 17, 1986 and (2) contain significant quantities of special study wastes as defined under RCRA sections 3001(b)(2) (drilling fluids), 3001(b)(3)(A)(ii) (mining wastes), and 301(b)(3)(A)(iii) (cement kiln dust). Before these sites can be added to the NPL, SARA requires that the following information be considered:

- The extent to which the HRS score for the facility is affected by the presence of the special study waste at or released from the facility.
- Available information as to the quantity, toxicity, and concentration of hazardous substances that are constituents of any special study waste at or released from the facility; the extent of or potential for release of such hazardous constituents; the exposure or potential exposure to human population and environment; and the degree of hazard to human health or the environment posed by the release of such hazardous constituents at the facility.

One site in this proposed NPL update—Carson River Mercury Site in Lyon and Churchill Counties, Nevada—contains or potentially contains special study wastes subject to the provisions of CERCLA section 105(g), specifically mining wastes. The Agency has placed in the dockets an addendum for this site that evaluates the information called for in section 105(g). This addendum indicates that the special study wastes at the site present a threat to human health and the environment, and that the site should be proposed to the NPL.

Section 125 of CERCLA, as amended by SARA, addresses special study wastes described in RCRA section 3001(b)(3)(A)(i) [fly ash and related wastes]. No sites in this rule are subject to the provisions of section 125.

Releases From Mining Sites

The Agency's position is that mining wastes may be hazardous substances, pollutants, or contaminants under CERCLA and, therefore, mining waste sites are eligible for the NPL. This position was affirmed in 1985 by the United States Court of Appeals for the District of Columbia Circuit (*Eagle-Picher Industries, Inc.* v. *EPA*, 759 F. 2d 922 (D.C. Cir 1985)).

Agency policy statements regarding including mining sites on the NPL are set out at 53 FR 23988, 23993 (June 24, 1988); 54 FR 10512, 10514–16 (March 13, 1989); and 54 FR 13296, 13300–01, 13302–03 (March 31, 1989). Today's rulemaking proposes to add 1 mining site—the Carson River Mercury Site in Lyon and Churchill Counties, Nevada—to the NPL.

V. Contents of Proposed NPL Update #10

Tables 1 and 2 following this preamble list 25 sites proposed for the NPL in Update #10. Each entry contains the name of the facility and the State and city or county in which it is located. All sites received HRS scores of 28.50 or above.

Each proposed site is placed by score in a group corresponding to groups of 50 sites presented within the final NPL. For example, a site in Group 8 of the proposed update has a score that falls within the range of scores covered by the eighth group of 50 sites on the final NPL. The NPL is arranged by HRS scores and is presented in groups of 50 to emphasize that minor differences in scores do not necessarily represent significantly different levels of risk. Federal facility sites are listed in a separate section of the NPL.

In the past, each entry was accompanied by one or more notations reflecting the status of response and cleanup activities at the site at the time this list was prepared. EPA is developing a report summarizing response activities at NPL sites, which the Agency believes will contain more timely and useful information on site status than did the response and cleanup codes. The report will be available shortly. In the interim, information on activities at the new proposed sites is available upon request to the appropriate Regional Office.

VI. Regulatory Impact Analysis

The costs of cleanup actions that may be taken at sites are not directly attributable to listing on the NPL, as explained below. Therefore, the Agency has determined that this rulemaking is not a "major" regulation under Executive Order 12291. EPA has conducted a preliminary analysis of the economic implications of today's proposal to add new sites. EPA believes that the kinds of economic effects associated with this proposed revision are generally similar to those identified in the regulatory impact analysis (RIA) prepared in 1982 for revisions to the NCP pursuant to section 105 of CERCLA (47 FR 31180, July 16, 1982) and the economic analysis prepared when amendments to the NCP were proposed (50 FR 5882, February 12, 1985). The Agency believes that the anticipated economic effects related to proposing the addition of these sites to the NPL can be characterized in terms of the conclusions of the earlier RIA and the most recent economic analysis. This rule was submitted to the Office of Management and Budget for review as required by Executive Order 12291.

Costs

EPA has determined that this proposed rulemaking is not a "major" regulation under Executive Order 12291 because inclusion of a site on the NPL does not itself impose any costs. It does not establish that EPA necessarily will undertake remedial action, nor does it require any action by a private party or determine its liability for site response costs. Costs that arise out of site responses result from site-by-site decisions about what actions to take, not directly from the act of listing itself. Nonetheless, it is useful to consider the costs associated with responding to all sites included in this proposed rulemaking.

The major events that follow the proposed listing of a site on the NPL are a search for potentially responsible parties and a Remedial Investigation/Feasibility Study (RI/FS) to determine if remedial actions will be undertaken at a site. Design and construction of the selected remedial alternative follow completion of the RI/FS, and operation and maintenance (O&M) activities may continue after construction has been completed.

EPA initially bears costs associated with responsible party searches. Responsible parties may bear some or all of the costs of the RI/FS, remedial design and construction, and O&M, or EPA and the States may share costs.

The State cost share for site cleanup activities has been amended by section 104 of SARA. For privately-owned sites, as well as at publicly-owned but not publicly-operated sites, EPA will pay for 100% of the costs of the RI/FS and remedial planning, and 90% of the costs associated with remedial action. The State will be responsible for 10% of the remedial action. For publicly-operated sites, the State cost share is at least 50% of all response costs at the site, including the RI/FS and remedial design and construction of the remedial action selected. After the remedy is built, costs fall into two categories:

- For restoration of ground water and surface water, EPA will share in startup costs according to the criteria in the previous paragraph for 10 years or until a sufficient level of protectiveness is achieved before the end of 10 years.
- For other cleanups, EPA will share for up to 1 year the cost of that portion of response needed to assure that a remedy is operational and functional. After that, the State assumes full responsibilities for O&M.

In previous NPL rulemakings, the Agency estimated the costs associated with these activities (RI/FS, remedial design, remedial action, and O&M) on an average per site and total cost basis. EPA will continue with this approach, using the most recent (1988) cost estimates available; these estimates are presented below. However, there is wide variation in costs for individual sites, depending on the amount, type, and extent of contamination. Additionally, EPA is unable to predict what portions of the total costs responsible parties will bear, since the distribution of costs depends on the extent of voluntary and negotiated response and the success of any cost-recovery actions.

Cost category	Average total cost per site [1]
RI/FS	1,100,000
Remedial Design	750,000
Remedial Action	[2] 13,500,000
Net present value of O&M [3]	[2] 3,770,000

[1] 1988 U.S. Dollars
[2] Includes State cost-share
[3] Assumes cost of O&M over 30 years, $400,000 for the first year and 10 percent discount rate.

Source: Office of Program Management, Office of Emergency and Remedial Response, U.S. EPA.

Costs to States associated with today's proposed rule arise from the required State cost-share of: (1) 10 percent of remedial actions and 10 percent of first-year O&M costs at privately-owned sites and sites that are publicly-owned but not publicly-operated; and (2) at least 50 percent of the remedial planning (RI/FS and remedial design), remedial action, and first-year O&M costs at publicly-operated sites. States will assume the cost for O&M after EPA's period of participation. Using the assumptions developed in the 1982 RIA for the NCP, EPA has assumed that 90 percent of the 23 non-Federal sites proposed for the NPL in this rule will be privately-owned and 10 percent will be State- or locally-operated. Therefore, using the budget projections presented above, the cost to States of undertaking Federal remedial planning and actions at all 23 non-Federal sites, but excluding O&M costs, would be approximately $46 million. State O&M costs cannot be accurately determined because EPA, as noted above, will share O&M costs for up to 10 years for restoration of ground water and surface water, and it is not known how many sites will require this treatment and for how long. However, based on past experience, EPA believes a reasonable estimate is that it will share startup costs for up to 10 years at 25 percent of sites. Using this estimate,

State O&M costs would be approximately $74 million.

Proposing a hazardous waste site for the NPL does not itself cause firms responsible for the site to bear costs. Nonetheless, a listing may induce firms to clean up the sites voluntarily, or it may act as a potential trigger for subsequent enforcement or cost-recovery actions. Such actions may impose costs on firms, but the decisions to take such actions are discretionary and made on a case-by-case basis. Consequently, precise estimates of these effects cannot be made. EPA does not believe that every site will be cleaned up by a responsible party. EPA cannot project at this time which firms or industry sectors will bear specific portions of the response costs, but the Agency considers: the volume and nature of the waste at the sites; the strength of the evidence linking the wastes at the site to the parties; the parties' ability to pay; and other factors when deciding whether and how to proceed against the parties.

Economy-wide effects of this proposed amendment to the NCP are aggregations of effects on firms and State and loal governments. Although effects could be felt by some individual firms and States, the total impact of this proposal on output, prices, and employment is expected to be negligible at the national level, as was the case in the 1982 RIA.

Benefits

The real benefits associated with today's proposal to place additional sites on the NPL are increased health and environmental protection as a result of increased public awareness of potential hazards. In addition to the potential for more Federally-financed remedial actions, expansion of the NPL could accelerate privately-financed, voluntary cleanup efforts. Proposing sites as national priority targets also may give States increased support for funding responses at particular sites.

As a result of the additional CERCLA remedies, there will be lower human exposure to high-risk chemicals, and higher-quality surface water, ground water, soil, and air. These benefits are expected to be significant, although difficult to estimate in advance of completing the RI/FS at these sites.

Associated with the costs are significant potential benefits and cost offsets. The distributional costs to firms or financing NPL remedies have corresponding "benefits" in that funds expended for a response generate employment, directly or indirectly (through purchased materials).

VII. Regulatory Flexibility Act Analysis

The Regulatory Flexibility Act of 1980 requires EPA to review the impacts of this action on small entities, or certify that the action will not have a significant impact on a substantial number of small entities. By small entities, the Act refers to small businesses, small government jurisdictions, and nonprofit organizations.

While this rule proposes revisions to the NCP, they are not typical regulatory changes since the revisions do not automatically impose costs. Proposing sites for the NPL does not in itself require any action by any private party, nor does it determine the liability of any party for the cost of cleanup at the site. Furhter, no identifiable groups are affected as a whole. As a consequence, it is hard to predict impacts on any group. A site's proposed inclusion on the NPL could increase the likelihood that adverse impacts to responsible parties (in the form of cleanup costs) will occur, but EPA cannot identify the potentially affected business at this time nor estimate the number of small businesses that might be afffected.

The Agency does expect that certain industries and firms within industries that have caused a proportionately high percentage of waste site problems could be significantly affected by CERCLA actions. However, EPA does not expect the impacts from the listing of these 25 sites to have a significant economic impact on a substantial number of small businesses.

In any case, economic impacts only would occur through enforcement and cost-recovery actions, which are taken at EPA's discretion on a site-by-site basis. EPA considers many factors when determining what enforcement actions to take, including not only the firm's contribution to the problem, but also the firm's ability to pay.

The impacts (from cost recovery) on small governments and nonprofit organizations would be determined on a similar case-by-case basis.

List of Subjects in 40 CFR Part 300

Air pollution control, Chemicals, Hazardous materials, Intergovernmental relations, Natural resources, Oil pollution, Reporting and recordkeeping requirements, Superfund, Waste treatment and disposal, Water pollution control, Water supply.

Dated: October 18, 1989.

Robert H. Wayland III,

Acting Deputy Assistant Administrator, Office of Solid Waste and Emergency Response.

PART 300—[AMENDED]

It is proposed to amend 40 CFR part 300 as follows:

1. The authority citation for part 300 continues to read as follows:

Authority: 42 U.S.C. 9605; 42 U.S.C. 9620; 33 U.S.C. 1321(c)(2); E.O. 11735 (38 FR 21243); E.O. 12580 (52 FR 2923).

Appendix B [Amended]

2. It is proposed to add the following sites by group to Appendix B of part 300

TABLE 1.—NATIONAL PRIORITIES LIST, PROPOSED UPDATE 10 SITES (BY GROUP)

[October 1989]

NPL gr [1]	St	Site name	City/county
4	CA	Industrial Waste Processing.	Fresno.
4	IL	MIG/Dewane Landfill.	Belvidere.
4	PA	Ohio River Park	Neville Island.
5	WI	Better Brite Chrome & Zinc Shops.	DePere.
6	AR	Monroe Auto Equip (Paragould Pit).	Paragould.
8	AK	Arctic Surplus	Fairbanks.
8	MN	Dakhue Sanitary Landfill.	Cannon Falls.
8	SD	Williams Pipe Line Disposal Pit.	Sioux Falls.
9	CA	United Heckathorn Co..	Richmond.
10	CA	Western Pacific Railroad Co..	Oroville.
10	NV	Carson River Mercury Site.	Lyon/Churchill cnty.
11	NJ	Chemical Insecticide Corp.	Edison township.
11	OR	Union Pacific Railroad Tie Treat.	The Dalles.
15	DE	Koppers Co., Inc. (Newport Plant).	Newport.
15	SC	Para-Chem Southern, Inc.	Simpsonville.
16	NE	Nebraska Ordnance Plant (Former).	Mead.
17	OK	Kerr-McGee Corp. (Cushing Plant).	Cushing.
17	FL	Anaconda Aluminum/Milgo Electron.	Miami.
18	MO	Westlake Landfill	Bridgeton.
18	AR	Magnolia City Landfill.	Magnolia.
18	NY	Sealand Restoration, Inc..	Lisbon.
19	NE	10th Street Site	Columbus.
19	PA	Dublin TCE Site	Dublin borough.

Number of Sites Proposed for Listing: 23.

[1] Sites are placed in groups (Gr) corresponding to groups of 50 on the final NPL

TABLE 2.—NATIONAL PRIORITIES LIST, FEDERAL FACILITY SITES, PROPOSED UPDATE 10 (BY GROUP)

[October 1989]

NPL gr [1]	St	Site name	City/county
12	CT	New London Submarine Base.	New London.
15	SD	Ellsworth Air Force Base.	Rapid City.

Number of Federal Facility Sites Proposed for Listing: 2.

[1] Sites are placed in groups (Gr) corresponding to groups of 50 on the final NPL

[FR Doc. 89-25279 Filed 10-25-89; 8:45 am]

BILLING CODE 6560-50-M